

29. A stretchable stent, comprising:

a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, the coiled-up sheet being expandable between a contracted condition and one or more enlarged conditions, the coiled-up sheet defining a periphery in a plane substantially perpendicular to a longitudinal axis thereof;

D, a plurality of locking elements extending from the inner longitudinal section for engaging openings in the outer longitudinal section to selectively secure the coiled-up sheet in the one or more enlarged conditions; and

a plurality of stretchable elements formed in the coiled-up sheet, the stretchable elements having a shape memory such that the stretchable elements are plastically deformable towards an unstretched condition at a temperature at or below about 25 degrees Celsius, and biased to expand about the periphery from the unstretched condition towards a stretched condition when exposed to a temperature at or above body temperature;

wherein each stretchable element comprises a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis.

REMARKS

Reconsideration of the rejections set forth in the Office Action mailed November 4, 2002 and entry of the present amendment is requested.

In the Office Action, the Examiner made the following objections and rejections of the listed drawings and claims:

- (1) The drawings were objected to for failing to show every feature of the claimed invention;
- (2) Claim 40 was objected to because it depended from a cancelled claim;
- (3) Claims 1-3, 5-10, 31, 33-40, 42, and 51-54 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,800,520 (“the Fogarty et al. patent” or “the ‘520 patent”);
- (4) Claims 15, 16, 20-22, and 43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Fogarty et al. patent in view of U.S. Patent No. 5,441,515 (“the Khosravi et al. patent” or “the ‘515 patent”);
- (5) Claims 29 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Fogarty et al. patent in view of the Khosravi patent and further in view of U.S. Patent No. 5,895,406 (“the Gray et al. patent” or “the ‘406 patent”);
- (6) Claims 44 and 45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Fogarty et al. patent in view of PCT Publication No. WO 95/31945 (“the Burmeister et al. publication”);
- (7) Claims 55-57 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Fogarty et al. patent in view of the Gray et al. patent; and
- (8) Claims 1-3, 8-10, 15, 16, 20, 51, and 52 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims from U.S. Patent No. 6,290,720.

In response, claims 1-3, 5-10, 15, 16, 20-22, 31, 33-40, 42-45, and 51-54 have been canceled without prejudice, and claim 29 has been amended. Applicants continue to respectfully disagree with the bases for the Examiner’s rejection of the cancelled claims, but wish to expedite prosecution of the claims remaining in the application. Thus, the cancellation of the above claims should not be

considered as an accession to the Examiner's rejections of those claims. Claims 29-30 and 55-57 are pending. Thus, of the above grounds, (2), (3), (4), (6), and (8) are obviated because they apply only to cancelled claims. The remaining objections and rejections are addressed below.

1. Objection to the Drawings

First, as to the objection to the drawings, the Examiner cites 37 C.F.R. 1.83(a) as the basis for the objection, stating that "the embodiment of a stent with a coiled sheet of expandable wing-like elements having a plurality of locking elements must be shown or the feature(s) cancelled from the claim(s)." Applicants respectfully submit that such embodiment is fully shown in the drawings in full compliance with section 1.83(a). For example, Figures 1A and 1B show a coiled-sheet stent 10 having, *inter alia*, "a plurality of stretchable elements 30 formed therein," (Spec., pg. 14, ll. 3-4), and having a first edge 20 "having a plurality of fingers or teeth 24 extending therefrom," (Spec. pg. 13, l. 21 to pg. 14, l. 1). As the specification further states: "The stretchable elements included in the coiled-sheet stents may take on a number of different forms." (Spec., pg. 22, ll. 21-22). Several of the forms of these stretchable elements are shown in the figures, including the "wing-like elements" shown in Figures 9, 10A, and 10B, (See Spec., pg. 28, l. 6 to pg. 29, l. 8). Thus, as required by section 1.83(a), the figures "show every feature of the invention specified in the claims," and the specification states that the features may be combined in alternative embodiments. It would be overly burdensome, unnecessary, and certainly beyond the requirements of section 1.83(a) to require applicants to show every embodiment of the disclosed invention, rather than every feature specified in the claims. Accordingly, applicants respectfully request reconsideration and withdrawal of the Examiner's objection to the drawings.

2. Rejections of Claims 29 and 30

Second, as to the Examiner's rejection of claims 29 and 30 on the basis of the combined teachings of the Fogarty, Khosravi, and Gray patents, applicants respectfully submit that there is no suggestion or motivation in any of these patents, or in the art as a whole, to combine the teachings of the three patents. The Fogarty patent describes a stent with an end having a terminal edge disposed at an oblique angle, including an embodiment comprising a coiled sheet. (Col. 5, ll. 3-12). Fogarty states that different elastic or other mechanical properties may be obtained by heat treating or by using different materials in different regions of the stent. (Col. 6, ll. 39-62). Nowhere does Fogarty teach or suggest that wing-like stretchable elements should be used "such that there is greater flexibility in the stent for more tortuous vessels." The Gray patent, on the other hand, describes a stent having a plurality of longitudinally disposed wave-like bands, (Col. 1, ll. 46-53), but nowhere does it teach or suggest that the bands should be used in a coiled-sheet stent. The Khosravi patent shows a stent having locking elements, but it does not suggest that the mesh pattern itself comprises an unstretched or peripherally contracted condition when the stent is in a contracted condition, and a stretched or peripherally expanded condition to facilitate expansion of the coiled-up sheet to one or more enlarged conditions. Nowhere is there a suggestion that the disparate teachings of these three patents could (or should) be combined in the manner suggested by the Examiner.

The Examiner's cited basis for making the combination – to obtain greater flexibility in the stent for more tortuous vessels – ignores Fogarty's teaching that this should be done through heat treatment or choice of materials. As a result, the only support for making the combination is to use Applicant's claims as a template, which is improper. Sensonics, Inc. v. Aerosonic Corp., 81 F.3d

1566, 1570 (Fed. Cir. 1996). “The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made.” Id.

Further, the Examiner’s stated basis is overly broad. Using the Examiner’s rationale, it would have been obvious to use the Gray et al. cell pattern in any stent. This simply goes too far. The Examiner is obliged to identify some basis for why a person of skill in the art would have been motivated to combine these references. Applicants respectfully submit that this has not been done.

In view of the above, Applicants respectfully submit that no prima facie case of obviousness is established as to claims 29 and 30, and that those claims are in condition for allowance.

3. Rejections of Claims 55-57


Finally, the Examiner rejected claims 55-57 on the basis of the combined teachings of the Fogarty and Gray patents. For the reasons set forth above, Applicants respectfully submit that there is no suggestion or motivation in either of these patents, or in the art as a whole, to combine their teachings. Thus, as with claims 29 and 30, Applicants respectfully submit that no prima facie case of obviousness is established as to claims 55-57, and that those claims are in condition for allowance.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

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VERSION WITH MARKINGS SHOWING CLAIM AMENDMENTS:

29. A stretchable stent, comprising:

a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, the coiled-up sheet being expandable between a contracted condition and one or more enlarged conditions, the coiled-up sheet defining a periphery in a plane substantially perpendicular to a longitudinal axis thereof;

a plurality of locking elements extending from the inner longitudinal section for engaging openings in the outer longitudinal section to selectively secure the coiled-up sheet in the one or more enlarged conditions; and

a plurality of stretchable elements formed in the coiled-up sheet, the stretchable elements having a shape memory such that the stretchable elements are plastically deformable towards an unstretched condition at a temperature at or below about 25 degrees Celsius, and biased to expand about the periphery from the unstretched condition towards a stretched condition when exposed to a temperature at or above body temperature;

[The stretchable stent of claim 16,] wherein each stretchable element comprises a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis.